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1. PREFACE

The regulatory environment in which clinical trials are conducted is continuing to change, such changes are generally focused upon requiring more rigorous control within the organisations in which clinical trials are performed in order to ensure patient safety and the reliability of data produced. The global acceptance of the ICH Guideline for Good Clinical Practice (GCP) and the implementation of the European Union Clinical Trials Directive (2001/20/EC) are two clear indicators of such change.

Whilst the EU Clinical Trials Directive and ICH GCP Guideline clearly specifies many requirements such as the role of the Ethics Committee, the Sponsor and the Investigator to name just a few, when it comes to defining the standards to be applied in the analysis of samples from a clinical trial they are very vague.

The EU Clinical Trial Directive indicates that guidance documents may be issued to define the requirements for various aspects of trials, but it is uncertain at this time as to whether these will include the analysis of trial samples.

The most applicable reference within ICH that indicate the standards required for the analysis of samples are in sections 2.13 "Systems with procedures that assure the quality of every aspect of the trial should be implemented", and in section 8 Essential Documents parts 8.2.12 and 8.3.7.

This document is intended to provide a framework to those organisations and individuals that undertake analyses of samples from clinical trials on the facilities, systems and procedures that should be present to assure the reliability, quality and integrity of the work and results generated during their contribution to a clinical trial.